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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,398	02/28/2002	Bruce A. Yankner	CMCC 654 DIV (2)	3779

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EXAMINER
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CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/11/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/086,398

Applicant(s)

YANKNER ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other:

**CLAIMS 23-29 ARE PRESENTED FOR EXAMINATION**

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 23-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoffman et al. (4,866,090); Wannamker et al. (5,350,758) and Spielvogel et al. (5,362,732).

Applicants' claims are drawn to compositions. Therefore, each of the references teaches a composition of one of the applicants' claimed compositions or a compound used in a biological pathway as claimed by applicants' claims 23, 24, 27 and 28.

Hoffman et al. teach at column 1, lines 5-65, column 2, line 50 to column 8, line 39 and column 9, lines 50-62 lovastatin, pravastatin and simvastatin of claim 24 and that each of these compounds inhibit cholesterol by inhibiting (claims 26 and 27) the enzyme, HMG CoA reductase as claimed in claim 24 and inherently decreasing the production of AB to decrease blood levels of claim 23,

Wannamaker et al. disclose and teach at column 2, lines 12-17 and column 2, line 20 to column 3, line 16 that the compounds taught therein have activity of inhibiting 2,3-oxidosqualene cyclase to inhibit cholesterol s claimed in applicants' claims 27 and

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28. The pharmaceutical compositions of the claimed biological pathway are taught at column 14, line 66 to column 14, line 44.

Spielbogel et al. Teach at column 8, lines 33-42 (see lines 38-42) a composition of claim 29 comprising nicotinic acid in a pharmaceutical formulation.

That applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the compositions encompassed by the claims. 23, 24, 27 and 28.

As stated in *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) "discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known compositions.

In other words, the biological effect of decreasing the production of AB (claim 23); wherein the compound inhibits uptake of dietary cholesterol (claim 26) ; wherein the composition blocks or decreases endogenous cholesterol production (claim 27) would be inherent in the compounds claimed.

Therefore, the rejection under 35 U.S.C. 102 (a) is deemed proper.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wannamaker et al. (5,350,738)

As stated above Wannamaker et al. teach the pharmaceutical formulation of compounds which inhibit 2,3-oxidosqualene cyclase to inhibit cholesterol as claimed in applicants' claim 26. The difference between this reference and applicants' claims 26 is that the reference fails to teach the uptake of dietary cholesterol. However, one skilled in the art would be motivated to use the compounds claimed in Wannamaker et al. to cause the uptake of dietary cholesterol since the reference teaches at column 16, lines 44-64 that the compounds can be within an oral form with an edible carrier.

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982,

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18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness is presented

None of the claims are allowed.

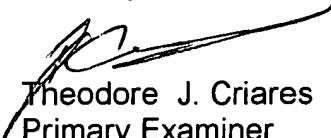
**CONCLUSION**

Applicants' claims are drawn to a composition of matter. However, they recite biological pathways which are inherent under 35 USC 102(a) in the compounds claimed. As such, the language fails to impart patentability to the claimed compositions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

  
Theodore J. Criares  
Primary Examiner  
Art Unit 1617

tjc  
June 11, 2003